Independent Safety Assessment (ISA) Product Certification Process

Issued on 13.02.2025

1.0 Objective

The objective of this document is to prescribe the evaluation process to be followed by BVIPL when evaluating manufacturers, importers and assemblers of product (hereinafter termed as manufacturers) against applicable requirements defined in the certification criteria of the Railway product under certification, to come to a reliable evaluation decision with respect to safety and security of the Product and maintain certification.

This document thereby aims to reduce the level of subjectivity, promote uniformity in the operation of the Scheme and increase the implementation consistency between different BVIPLs across different situations, desirous of operating the Certification Scheme.

2.0 Scope

This Certification Process is applicable to product /components of Product being manufactured by manufacturers and importers of Product in India. For ease, both manufacturers and importers are being termed as manufacturer under this Product certification Scheme.

Product under Product Certification is as below: --

Sl. No.	ISA Scope	System/ Product	Relevant Standard
1	Independent Safety Assessment. Energy	• Power Equipment's • Pantograph • Overhead Contact lines • Others	1) Procedure for safety certification and technical clearance of metro system by RDSO, 2015 (Indian Railway Guidelines, Indian Railway/ RDSO Standards, IS Specification, National/ International Standards applicable to Rolling Stocks i.e EN. UIC, AAR, ICF/RCF specifications, IS.) 2) CENELEC EN 50129: 2018- Railway applications - Communication, signalling and processing systems - Safety related electronic systems for signalling. 3) CENELEC EN 50206 – Part 2:2010 is a European standard that specifies the characteristics and tests for pantographs and traction systems on rolling stock. 4) EN 50121-1: 2017- Railway Application- Electromagnetic Compatibility - Part 1: General 5) EN 13260+A1: This standard applies to wheelsets that use components that meet the requirements of EN 13261 for axles and EN 13262 for wheels. 6) EN 13261: This standard specifies the requirements for axles. 7) CENELEC EN 50126-1: 2017 (Part 1) Railway applications - The Specification and Demonstration of Reliability, Availability, Maintainability, and Safety (RAMS) –Part 1: Generic RAMS Process. 8) CENELEC EN 50126-2: 2017 (Part II - 2017+A1:2024) Railway applications - The Specification and Demonstration of Reliability, Availability, Maintainability, and Safety (RAMS) –Part 2: System Approach to Safety 9) CENELEC EN 50128: 2011+A2:2020 Railway applications - Communications, signalling and processing systems- Software for railway control and protection systems. 10) CENELEC EN 50159: 2010+A1:2020- Railway Application- Communication, Signalling and Processing system. Safety related communication in
2	Independent Safety Assessment Control Signaling & Communication - Main Line - Metro Line - Generic of Product	• Train Protection & Supervision system – ATS, ATP, ATO, others. • Radio communication system • PSD • Train Detection system- Axle Counter, Track Circuit, others.	

			transmission system.
3	Independent Safety Assessment and Certification for Railway System, Rolling Stock	Wagon/Locomotives/Metro Cars/ICF/LHB coaches	1) CENELEC EN-50657 :2017+A1:2023 Railways Applications - Rolling Stock Applications - Software On Board Rolling Stock. 2) EN 13749:2021 This standard specifies the requirements for the design of bogie frames, Method of specifying the structural requirements of bogie frames 3) EN 13261:2020 - Railway applications, Wheelsets and bogies, Axles, Product requirements. 4) EN 13262:2020 - Railway application, Wheelsets and bogies, Wheels, Product requirements. 5) RDSO Rules 6) Coach / wagon – Wheels & Wheel sets IRS R-19/93 Part 1 (Corrigendum-1, 2,3), Steel axle IRS R-16/95 (Corrigendum-1, 2,3 & 4), Solid Forged Wheel IRS R-19/93 Part-II (Rev-05). 7) Specification no. RDSO/ SPN/144/ 2006 Revision: 2 - Safety And Reliability Requirement Of Electronic Signalling Equipment. 8) RDSO/SPN/192/2019 Ver. 2 - Electronic interlocking. 9) RDSO/SPN/196/2020 Ver. 4.0 - KAVACH (The Indian Railway Automatic Train Protection System). 10) Master List of Drawings Wagon –Wise (Updated up to 31.12.2024)

This document specifies the requirements and procedures to be followed by the manufacturers in India seeking and thereafter maintaining certification of the Product and Bureau Veritas to evaluate the Product in order to establish conformity to applicable certification requirements as per the certification criteria for Product. The certification is granted only against the Product Certification Criteria defined under the Scheme.

The certification of the manufacturer shall be carried out by Bureau Veritas (India) Private Limited duly accredited for the certification scheme as per ISO/IEC 17065 by AB.

Note –Shall requirement is mandatory requirement.
Should requirement be recommended requirement.

3.0 Maintenance

The TIQ Manager maintains this procedure.

4.0 Responsibility

The Certification manager/Technical manager shall be responsible.

5.0 Criteria of Certification

ISO 17065-2012 standard, Quality Manual and internal procedure including acceptance criteria as mentioned in CENLEC standard.

6.0 References:

- Product Certification & acceptance Criteria.
- Type 1A for type testing as per 17067:2012.

7.0 Certification Process

7.1 General

7.1.1 This Quality manual consists of two product certification schemes, one of them is Independent Safety Assessment scheme type A certification.

7.1.2 Specified standards & Normative references are as below

- ISO 17065 standard.
- RDSO & Internal procedure requirement for Railway Signalling system product certification,
- IP 14 Scheme procedure
- Certification Process IP 05, Quality Manual, and Internal Procedure
- Type 1A for type testing as per 17067:2012.
- EN 50126 Series applicable for Safety
- CENELEC standards DIN EN 5012x
- Functional safety IEC 61508
- National rules and regulations
- BVIPL Website - https://www.bureauveritas.co.in/isa-independent-safety-assessment

Bureau Veritas shall maintain and make publicly available accurate up-to-date information describing the evaluation and certification procedures for granting, maintaining, extending, renewing, reducing, suspending or withdrawing certification for the Product under scheme.

BVIPL provides information about suspensions and withdrawals, is available to interested party by contacting the certification entity except If specifically required by Accreditation body or regulatory bodies then it will be provided once the identification details are entered on the BVIPL website. Refer Appendix 19 public information latest.

7.1.3 The ISA scheme has been designed by Product owner & TIQ manager and established the requirement in Internal Procedure 14.
Bureau Veritas request to fill up the Application form which contains following as minimum, scope of certification sought by the applicant with details of manufacturer's name, Product/component no. description, details with component, equipment details, performance details etc, a typical application form of product under certification. An applicant in one application can apply for more than one product.

Note – Each product shall be evaluated for compliance to all applicable requirements certification criteria.

i. Documents confirming the Indian legal entity of the manufacturer.
ii. Documents relating to authorizations and permissions required as per Central Government Rule and Regulations.
iii. The manufacturer of Product should obtain if any regulatory/ statutory/ Voluntary approval if any.

iv. Documents
   a. Details of Designed considering safety aspects.
   b. Design appraisal.
   c. Analysis Reports and Test reports
   d. Product manual / Product logbook/ manufacturers operating manual
   e. Maintenance manual

v. Maintenance inspection schedule
vi. Other relevant reports
vii. Any information considered essential for determining auditor competence and estimation of auditor man-days.
viii. Information about any judicial proceedings relating to its operations, any proceedings by any Regulatory body or suspension/cancellation/withdrawal of any relevant approvals/ certifications under any Regulations or otherwise.

7.2 Application

Application for certification - Any manufacturer of Product (hereafter called an applicant) can apply for certification of Product specifying the specific scope of certification to BVIPL, for the scope approved by Accreditation Body (AB).
Application is to be applied through Application form along with supporting documents mentioning the complete details as below.

1) The Product to be certified
2) Standard & Normative documents which clients seeking certification.
3) The name and address of the applicant
4) Details about Inspection facilities & Lab (if owned lab is available)
5) Human & Technical resources available
6) Outsourced processes related to product under certification, if outsourced processes related to product is affecting the conformity assessment then contractual requirement to be set with manufacturer (such as surveillance at outsourced activities) to ensure that the outsourced process meet the conformity assessment requirement.
7) Location of evaluation & surveillance (if surveillance is applicable)
8) Reference to the Product Certification requirement in IP 14 for - Certification for which certification services are being offered,
9) Procedure for obtaining Certification.
10) Application form
11) List of documents required to be submitted along with the application.
12) Information on fee for application, initial evaluation and validity status
    Refer Manufacturer application form – Appendix 3
13) The above information along with the application format shall be made available on manufacturer website.
14) The applicant shall apply on the Application form, along with supporting documents as identified in the Application Form to Bureau Veritas.
15) Bureau Veritas shall respond to all enquiries received from applicants for certification with complete information for facilitating a registration of an applicant, within seven working days of receipt of the query.

16) The prospective applicant manufacturer shall declare whether it has been an applicant/certified under this Scheme with or by any other BV entity or any other IB/CB, and if yes then shall provide the previous audit reports to Bureau Veritas. Bureau Veritas may verify the information provided by contacting with other BV Entity or any other CB.
17) Certification is granted only against the current relevant certification criteria for Product. Bureau Veritas shall review all applications for the above and ensure the same.

7.3 Application Review

7.3.1 All applications for certification shall be reviewed by Bureau Veritas for adequacy, and deficiencies observed, if any, shall be informed to applicant within seven days of receipt of application. Review of applications shall be done by a competent and authorized person for ensuring the following.

a. The information about the manufacturer, facilities, Product details, scope of certification is sufficient for the conduct of the application review and the subsequent certification process.
b. Any known difference in understanding between Bureau Veritas and the applicant is resolved, including agreement regarding certification criteria.
c. The scope of certification sought is defined.
d. The means are available to perform all evaluation activities.
e. Bureau Veritas has the competence and capability to perform the certification activity.
f. To determine the time required for conduct of the on-site evaluation (single stage initial evaluation and renewal evaluation) depending upon the number Product applied for by the applicant. The basis to ascertain the duration of Initial valuation as well as the renewal evaluation shall be the same.
g. To determine and nominate an evaluation team, evaluator and the technical reviewer competent for the certification scope applied for. This shall be done in accordance with the requirements specified in the Certification Scheme document Certification Process". Records of review shall be maintained.
h. If any competency is not available with Bureau Veritas then other alternative will be identified or if not possible then application will be declined.

7.3.2 Additionally, the review of application shall also ensure the following:

a. The availability of the applicable Certification Scheme Certification Criteria in the English language.
b. The means are available to perform the certification activity.
c. Examination of the licenses issued by the regulatory body. The applicants shall have a valid authorization/ license to undertake their business operations, as applicable.
d. That application is for a single Manufacturer's only. Under the Scheme the certification granted is to Manufacturer, which may have applied for multiple product/components of product under certification.
e. Also to check that normative & standard references are mentioned in the application.
Refer application review checklist – Appendix 29

Based on the review of applications for certification, deficiencies observed, if any, shall be informed to applicant within a reasonable time. Records of review shall be maintained. In case the information about the applicant and the Product to be certified, as provided by the applicant, is not complete/sufficient for the purpose of conducting an application review then Bureau Veritas will have procedure for obtaining additional information. The information thus received shall be recorded along with other information already received.

Only applications found to be completely filled and supported with all documents sought shall be accepted and registered in order of receipt with a unique identification/File number, acknowledged and communicated to the applicant, and records maintained. Bureau Veritas shall ensure traceability from the point of acceptance of the application/Product until the issuance of certificate.

Queries, if any queries, shall be sent to the applicant. Alternatively, the queries may also be sent Product owner.

BVIPL shall ensure traceability from the point of acceptance of the application/Product until the issuance of statement of conformity.

Antecedents of applicants shall be verified. If penalized under the law, the application from the same manufacturers will not be entertained during the period of penalty and in any case for at least one year from the date of imposition of penalty.

Applications from manufacturers(s) who have earlier either misused the Certification or the certification mark, or whose earlier Certificate was cancelled because of violation of terms and conditions/misuse of certification mark shall not be entertained within six months of cancellation of the certificate by any BVIPL.

Applications from manufacturers(s) found to be misusing the Certification/certification Mark while their application is being processed for grant of certificate, shall not be processed any further, and rejected after giving a due notice of 15 days. Fresh applications shall be processed like a fresh applicant.

Requests for grant of certificates from ex-applicants shall be processed like a fresh applicant and the entire procedure for grant of certificate be adhered to.

The BVIPL shall clearly understand its responsibilities, abide to the same by designing documentation and adhering to requirements mentioned for the authorised CB as prescribed in certification scheme.

Bureau Veritas shall clearly identify the responsibilities and adhere to the internal timelines as prescribed by scheme for responding to enquiries from prospective applicants, applicants, application review and feedback to manufacturers electronically.

Bureau Veritas (India) Private Limited shall reject or close an application under the following conditions.

a. If Initial Evaluation is not carried out within two months of registration of application as notified in the scheme documents.
b. Misuse of Certification/certification mark,
c. Adverse incident reporting,
d. Evidence of malpractice and
e. Voluntary withdrawal of application.

Checklist appendix 29 will be filled out by Application reviewer for above compliances.

7.3.3 The certification body will ensure the competency during the offer / contract review stage and record will be maintained. **Refer Appendix 29 – Application reviewer checklist**.

7.3.4 During the application review stage, if the competency is not available then the contract will be declined & information will be sent to the client. **Refer Appendix 29**.

7.3.5 If any existing certificate is available with the client & the request received from the client to omit any part Of the scope then CB will decide and will inform to the client accordingly.

7.4 Evaluation

7.4.1 The evaluation shall be conducted in two stages namely stage 1 - document review and stage 2 - evaluation of performances and Testing, **refer evaluation plan Appendix 4.**

The duration of stage 1 and stage 2 including testing of initial evaluation of new applicants or already certified Product (manufacturer) requesting for revision, shall be same for every Product/component of Product covered in the scope of certification. Any deviation should be recorded and justified by the BVIPL.

7.4.2 The personnel will be identified in evaluation plan to perform each evaluation task. Including if any outsourced activities.

7.4.3 BVIPL application reviewer will ensure that all applicable documentation & information's is available during application review stage.

All evaluations, including renewal of certification shall evaluate all the requirements of Product.
Certification criteria applicable to the Product/component(s) of Product covered in the scope of certification.

7.4.4 The minimum duration of a stage 1 evaluation for one Product/component of Product shall not be more than 6 man-days, while that for stage 2 shall not be more than 8 man-days. **Refer Appendix 8 - contract review checklist.**

It may be noted that while the minimum evaluation time is established for the evaluation of one Product/component or identical Product (refer 7.4.3), it does not include the time for preparation of the evaluation nor for writing the evaluation report, or time spent for travelling. It will be done on the basis of evaluation plan & resources identified internally & externally.

The number of evaluators per evaluation day shall take into consideration the effectiveness of the evaluation, the resources of the manufacturer being evaluated as well as the resources of the BVIPL. Where additional meetings are necessary, e.g. review meetings, coordination, evaluation team briefing, an increase in evaluation time may be required.

Timings and date of evaluation shall be fixed in consultation with the applicant, ensuring that the
Complete evaluation including the test be carried out. The duration and the evaluation plan for evaluation shall be informed in advance to the applicant.

The BVIPL shall communicate the composition of the team, along with their respective curriculum vitae, to the applicant for verifying any conflict of interest. Any objections to the team composition by the applicant should be examined by the BVIPL on merit. If required by the applicant, sufficient background information in respect of the evaluation team members shall be provided for this purpose. Any objections to the team by the applicant shall be examined on merit.

7.4.5 CB will not outsource any evaluation activities as such, testing activities will be under manufacturer scope & accordingly contract requirements will be taken care of, while all lab testing is to be carried out in accredited Lab.
The information gathered during stage 1 evaluation shall be used for making adjustment in evaluation time and/or evaluation team competence for stage 2 evaluation, as necessary.

Prior to undertaking the site visit, the BVIPL, through the members of its nominated team, shall undertake certain off-site activities as part of preparation and planning stage. These are:

i. Study of all the information received and request for additional information, if required.
ii. Based on the scope of certification applied, identify the applicable certification criteria requirements.
iii. Prepare an initial evaluation plan for stage 1 and stage 2 evaluation.

Evaluation Process

Stage 1 Evaluation

The Objectives of stage 1 evaluation shall be:

i. To review the documents and records submitted by the applicant, for each of the Product/component applied for compliance to the applicable requirements of the Product certification criteria.
ii. To review and revise, if required, an evaluation plan for stage 2 evaluation.

7.4.6 Deficiencies (non-conformities) observed with respect to the certification criteria during Stage 1 shall indicate non-compliance with respect to applicable requirements of the Product certification criteria. No further categorisation of deficiencies/non-conformities is done.

In case any non-compliance with respect to a particular Product/component is observed, the BVIPL shall ask the applicant to submit a set of documents and records to indicate the compliance as per the applicable clause with fresh sample, as applicable for the relevant product /component.

The evaluation team shall prepare a report highlighting the level of compliance for each of the applicable requirement for every Product/component as per the scope of certification including the deficiencies. As and when the deficiency is observed, a recommendation should be made for holding the certification until a stipulated time so that the applicant may submit the compliant records, documents and equipment as may be the case.

On completion of the stipulated time, a recommendation should be made for the discontinuation of the certification process and closure of the certification as notified in the Certification scheme.

Stage 2 Evaluation

The Stage 2 evaluation by BVIPL shall take place only when all the applicable requirements of the product certification criteria have been evaluated in stage 1, compliance to the requirements have been observed and no major deficiencies (non-conformities) have been recorded.

The objective of the stage 2 evaluation shall be:

i. The stage 2 evaluation shall cover on-site testing, Product testing at manufacture for each of the Product/components of Product applied for in the scope of application. Witness of testing and Product test shall be carried out as part of the stage 2 evaluation.
ii. Product shall be evaluated for safety and security requirements. To enable this, necessary information relating safety aspects and other information to enable their evaluation shall be collected from the applicant. On the basis of satisfactory reporting, the evaluation team shall validate the same on-site at the applicant's site for compliance. applicant on-site shall be witnessed by the BVIPL evaluation team.

iii. The test Product conducted by the manufacturer at an approved site, shall be witnessed by the evaluation team for compliance. The manufacturer shall give necessary information on completion of the Product test. On completion of the test Product, the evaluation team shall obtain the details and the necessary information from the manufacturer for verification. The BVIPL team shall collect the details of report/record and other information for validation/verification provided to them by the manufacturer.

7.4.7 Deficiencies (non-conformities) observed with respect to the certification criteria during the Stage 2 shall indicate non-compliance with respect to applicable requirements of the Product certification Criteria.

If client wants to continue the certification process after observing the non-conformities then CB will decide if any additional evaluation tasks needed to verify that nonconformities have been corrected.

As and when the deficiency observed, a recommendation made for holding the certification until the stipulated time so that the applicant may submit the conformance report, documents and equipment as may be the case. On completion of the stipulated time, a recommendation made for the discontinuation of the certification process and closure of the certification.

In case any non-compliance with respect to a particular Product/components observed by the BVIPL, a recommendation made for holding the certification until a maximum period of sixty days so that the applicant may submit the conformance report, documents and equipment as may be the case. On completion of the stipulated time, a recommendation made for the discontinuation of the certification process and closure of the certification.

7.4.8 If the client agrees to completion of the additional evaluation tasks, the process specified in 7.4 shall be repeated to complete the additional evaluation tasks.

Performance Testing Witness

During the process of evaluation, the testing and performance conducted by the applicant on-site shall witness by the BVIPL evaluation team. The BVIPL shall satisfy itself about the process or would require repeating the testing on-site.

When the testing conducted by the applicant on-site witnessed by the BVIPL evaluation team, this would be considered as independent testing.

All tests conducted by the applicant (Product test) witnessed by the BVIPL evaluators shall consider as equivalent to independent testing of Product Product/components.

The test certificate shall be from accredited lab to ISO/IEC 17025 by Indian accreditation body like National Accreditation Board for Testing and Calibration Laboratories (NABL) or by any other foreign accreditation body working in accordance with ISO/IEC 17011 having relevant scope of accreditation, for ascertaining conformance to the tests results or the laboratory has implemented ISO 17025 in respect of clauses pertaining to technical competence aspects – competence of testing personnel, test facilities, use of validated test methods, traceability/calibration of equipment, sampling, sample handling, Internal quality assurance aspects, etc.

Note: Some of the mentioned tests in the certification criteria may be out of scope of accreditation for the laboratory. The test reports from a laboratory that has established systems as per 17025 may be accepted by the BVIPL for giving a decision for approval.

There shall have a formal contract by manufacturer with the sub-contracted laboratories for provision of competent services and for ensuring aspects like impartiality and confidentiality as relevant.

If the BVIPL uses an in-house laboratory (part of the same legal entity), it shall be ensured that there exists an adequate separation, in terms of organization structure and reporting and defined responsibilities. It shall also ensure through above means, policies, and procedures, that there is no possibility of compromising the independence of the testing laboratory personnel by bringing undue pressure over them.

The certification criteria against which Product is to be tested or if in case of complaint shall be clearly mentioned and communicated to the testing laboratory. The sample(s) shall be so dispatched that they do not get damaged or contaminated, undergo deterioration, and the Product integrity is maintained. The BVIPL shall have a documented procedure for drawing of samples, The procedure shall also include aspects like receipt of test reports and their evaluation.
This witness test is to be recorded in **Appendix 14.**

7.4.9 Final Evaluation

The purpose of this step is to conduct an evaluation of all the information gathered through Stage 1 and Stage 2 evaluation and the results of independent testing:

i. to ascertain if all the process steps as described in the certification process leading to grant of certificate have been fulfilled,
ii. to confirm that the Product/component applied for as per scope of application complies with requirements described in the relevant certification criteria.

The final evaluation shall ensure compliance to the certification requirement and any other requirements prescribed by the BVIPL, and no non-conformances observed.

Based on the evaluation as above, recommendations for proceeding to next step (independent review and decision making) shall be made. In case the evaluation indicates that some requirements of the certification criteria or the

certification scheme have not been met and then these need to be completed and evaluated before proceeding to the next step.

The final evaluation shall be carried out by competent personnel, duly authorised for this function. The team leader designated for the conduct of Initial Evaluation may also be authorised for this activity.

Records of final evaluation along with all supporting documents and reports shall be retained at least for the period of 5 years, whichever is later.
Evaluation Checklist to be filled as per **Appendix 9**
Evaluation report will be issued in **Appendix 10 (A,B,&C) & Appendix 15 (A,B,&C).**

7.5 Review

7.5.1 An independent review shall be carried out by person(s) or a committee having the relevant competence, duly authorised for this purpose. The responsibility for review function, shall however be that of the BVIPL. Review and certification decision may be completed concurrently by the same person(s) or committee. The Review record will be done by using technical reviewer checklist - **Refer appendix 26.**

The criteria for review shall be documented. It shall be based on the Product requirements for each of the Product/component for which certification is sought as specified in Certification Criteria and the certification scheme and process requirements as stated in this document.

Any information on which a review and decision is based which comes from any source other than the evaluation process, for example complaints, adverse incident reporting, information received from regulators, etc., shall be made known to the applicant along with information on the evaluation process through the by mail.

7.5.2 The recommendation will be done by the technical reviewer, who will not be a part of the evaluation & will be recorded. The certification decision will be taken on the basis of recommendation by technical reviewer.

The records of review shall be retained and shall provide adequate confidence that all relevant aspects were examined prior to making recommendations.

The recommendation for evaluation decisions, whether positive or negative shall justify and document the basis for the same.

7.6 Certification Decision

7.6.1 Evaluation decision shall be the sole responsibility of the BVIPL, and the decision shall be taken by its person(s) competent for the job provided they have not been involved in the process of evaluation of the Product of this applicant.

7.6.2 The decision maker will be assigned such as, the person(s), who take(s) the decision on granting/withdrawing certification shall be competent to evaluate the information obtained from the evaluation process and the review recommendations. Review and the evaluation decision may be completed concurrently by the same person (s).

The BVIPL shall communicate recommendation to client for the certification of product/component applied for the Scope of certification after ensuring complete compliance to the certification criteria, certification scheme and certification process requirements and ensuring no non-conformance exists.

7.6.3 Impartiality and absence of conflict of interest shall be ensured before entrusting the task of evaluation decision making & he will not be a part of other committee as per cl.5.1.4

7.6.4 BVIPL is a legal entity & Inspection department is a part of this legal entity.

7.6.5 BVIPL contractual employees (non-exclusive) or any entity under control of BVIPL handling any of the related part of ISA certification if any will comply same requirements as BVIPL regular employees and BVIPL certification requirement of established standard & Scheme, such as qualification, supervision & monitoring, training etc.

7.6.6 In case, based on the evaluation the BVIPL decides, not to grant certification for any or all components of Product under certification communicated Product applied for, it shall notify the applicant of the decision by mail on components for which certification has not been granted along with reasons for the decisions shall be communicated to the applicant by mail. If the applicant expresses interest in continuing the certification process, the BVIPL can resume the process for evaluation from the process as described from clause 7 onwards. Decision maker will carry out the decision by reviewing the checklist Appendix 20.

7.7 Certification Documentation

7.7.1 Certification documents will consist of conformity of certificate – **Refer Appendix 12.**

In this scheme for product certification which based on Type 1 A as per ISO 17067:2012, one or more samples of the each of the component of the product are subjected to the determination activities. A statement of conformity (e.g. a letter) is issued for component/product by mail, the characteristics of which are detailed in the certificate, or a document referred to in the statement of conformity.

On completion of evaluation, the BVIPL shall inform the applicant and issue a statement of conformity (e.g. a letter), uniquely identified, which shall include the following information:

i. the name and address of the BVIPL.
ii. the name and address of the applicant
iii. the certification criteria against which the certification has been awarded reference to the certification criteria document shall include issue number and/or revision, used for evaluation of the applicant.
iv. the scope of certification shall include category, Product / component, along with their intended use/application for each of the product/component including and the date from which valid categories certified:
v. the effective date (the date on which statement of conformity is granted, which shall not precede the date on which the certification decision was completed). The date of granting shall also include date of extending or renewing the certification, if applicable.
vi. the expiry date or recertification due date consistent with the recertification cycle.
vii. The maximum validity period of this statement of conformity will be 5 years from the date of decision to grant the certification.
viii. Any other information required by the certification criteria used for certification.
ix. In the event of issuing any revised certification documents, a means to distinguish the revised documents from any prior obsolete documents.
x. The formal certification documentation shall include the signature of the individual(s) of the BVIPL assigned such responsibility.

7.7.2 Conformity of certificate will be signed by the certification decision maker – **Refer Appendix 1.**

7.7.3 Formal certification documentation shall only be issued after, or concurrent with, the following:

i. the decision to grant or extend the scope of certification (see 7.7.1) has been made by BVIPL.
ii. certification requirements have been fulfilled.
iii. the certification agreement has been completed/signed.
iv. the use of certification mark agreement with BVIPL NABCB, is signed and submitted by the manufacturer of the certified Product/component to BVIPL/NABCB through the BVIPL only on after the grant and issuance of Type Certificate by BVIPL.

The Evaluation Report

The evaluation reports for stage 1 and stage 2 shall clearly provide evidence and conclusions about the fulfilment of the evaluation objectives as described above and shall contain sufficient detailed information regarding conformity with all the relevant certification requirements, including the Certification Criteria for each Product/component singularly. The BVIPL shall develop appropriate report format(s) and report writing guidance document to ensure that the report provides, adequate and complete details for ensuring appropriate, evaluation, review and decision in respect of grant of certification.
This evaluation report along with the statement of conformity shall be completed within 60 days of after receipt of Application by BVIPL will Stage 1 and Stage 2 satisfactory completion and satisfactory closure of finding by Manufacturer.

7.8 Directory of Certified products

The BVIPL shall maintain and make directory of valid certifications issued by BVIPL that as a minimum shall show the name, relevant certification criteria (normative document), scope and geographical location (e.g. city and country) for each manufacturer and validity of certification, and this information will be given to AB as and when required. It will be recorded in **Appendix 21.**

The information maintained by the BVIPL on its website publically available shall also help the user to get readily the following information about the certified product /component:

i. shall include the Product /component certified for intended use,
ii. the standard(s) and other normative document(s) to which conformity has been certified.
iii. name of the certified product /component,

The BVIPL shall also keep the record suitably on the names of manufacturer under suspension by BVIPL and those whose certificates have been cancelled.

Apart from the information made available on its website the BVIPL shall also have a provision and system for confirming validity of a certificate issued by BVIPL on request.
The BVIPL shall have a procedure for frequent updating of the information on its website.

7.9 Surveillance

Surveillance is not applicable.

7.10 Changes affecting certification.

7.10.1 When the certification scheme introduces new or revised requirements both in Certification scheme of Product, Certification Criteria and Certification Process requirements that affect the applicants and the certified manufacturer, Bureau Veritas shall ensure these changes are communicated to them.

Bureau Veritas shall advise the applicant and the certified manufacturer as relevant to apply for certification limited to delta compliance which shall be processed accordingly. Delta Compliance covers specific type test schedule which shall take care of all the aspects including safety and security of the equipment pertaining to the requested changes.

The contractual agreement with the manufacturer certified under this Scheme shall have clearly defined clause, which shall make it makes mandatory for the applicant/certified manufacturer to submit an application for certification to verify delta compliance necessitated due to changes in the certification criteria and certification process requirement.

7.10.2 The changes initiated by the client affecting the certification will also be considered by the certification body.

7.10.3 The actions to implement changes affecting certification shall include, if required, the following:

i. evaluation (see 7.4);
ii. review (see 7.5);
iii. decision (see 7.6);
iv. issuance of revised formal certification documentation (see 7.7) to extend or reduce the scope of certification;
v. issuance of certification documentation of revised surveillance activities (if surveillance is part of the certification scheme).

These actions shall be completed in accordance with applicable parts of 7.4, 7.5, 7.6, 7.7 and 7.8. Records (see 7.12) shall include the rationale for excluding any of the above activities (e.g. when a certification requirement that is not a product requirement changes, and no evaluation, review or decision activities are necessary). If any transfer of certificate then refer Appendix 37.

The certified manufacturer shall be bound by the certification agreement to inform Bureau Veritas about changes initiated in the product /component /module by the certified manufacturer.

7.11 Termination, reduction, suspension or withdrawal of certification

7.11.1 The BVIPL shall recommend the suspension/withdrawal of the certificate to BVIPL when:

a) a non-certified Product/component is marketed as a certified product /component.
b) adverse event/incident reporting and or complaints are received.
c) failure of any Product/component to comply to the certification requirements at the time of renewal.
d) the manufacturer has voluntarily requested a suspension or withdrawal.
e) Any other administrative reason like non-payment of fee etc.

7.11.2 When the appropriate action includes evaluation, review or a certification decision, the requirements in 7.4, 7.5 or 7.6, respectively, shall be fulfilled.

7.11.3 The Product /Component manufacturer shall be informed that the certification has been recommended for suspension (for partial or complete for a particular scope of certification) and while under suspension, the manufacturer certificate is temporarily invalid. The manufacturer shall be advised to suspend operation of particular Product certification and not to make any misleading claims during the period of suspension and should advise relevant existing and potential purchasers regarding the status of certificate, and ceases to use the certification mark that may be used in publicity material, pamphlet, letterheads, other similar stationary, media for exchange of any communication, for promoting the awareness of the scheme since the date of notification of suspension.

On receipt of instructions for suspension of certificate, the manufacturer shall suspend using the certification mark on that may be used in publicity material, pamphlet, letterheads, other similar stationary, media for exchange of any communication, for promoting the awareness of the scheme with immediate effect and proceed for the reduction of Scope. If desirous, the manufacturer shall apply afresh for the Product /components that have been removed from the scope of certification.

A BVIPL shall ensure that the product manufacturer has procedures in place to ensure that a non-certified product/component, shown as to be a certified Product/component shall be recalled.

While under suspension, the BVIPL shall ensure that despatches of certified Product /components are withheld.

The information about the suspension and withdrawal of certificate shall be made available by the two interested parties as and when required suitably.

The BVIPL shall recommend the revoke of suspension of certificate to BVIPL, only in case if it is due to administrative reasons, the same shall be revoked when the manufacturer has taken suitable action, which have been verified and found suitable by the BVIPL.

Suspension shall not exceed a period of six months. The manufacturer's inability to resolve issues related to reasons for administrative reasons to suspension within this period shall lead to cancellation of certification by BVIPL.

The BVIPL shall recommend for the withdrawal of the certificate to the BVIPL at the request of the manufacturer, if the product manufacturing in the manufacturer's premises can no longer be carried due to reasons of natural calamities such as flood, fire, earthquake etc., lock out declared by the management, or closure of business operations etc.

7.11.4 If certification is suspended, the BVIPL shall assign one or more persons to formulate and communicate the following to the client:

i. actions needed to end suspension and restore certification for the product(s) in accordance with the certification scheme;
ii. any other actions required by the certification scheme is that the competent person will assigned to handle the aspect of suspended certificate. In this case technical reviewer will look into the matter.

The competent person such as technical reviewer who is having knowledge and understanding of all aspects of the handling of suspended certifications (see 6.1).

7.11.5 Any evaluations, reviews or decisions needed to resolve the suspension, or that are required by the certification scheme, shall be completed in accordance with the applicable parts of 7.4, 7.5, 7.6, 7.7.3, 7.9 and 7.11.3.

7.11.6 If certification is reinstated after suspension, the BVIPL shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure all appropriate indications, exist that the product continues to be certified. If a decision to reduce the scope of certification is made as a condition of reinstatement, the BVIPL shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the client and clearly specified in certification documentation and public information.

7.12 Records

7.12.1 The BVIPL shall have a documented policy and documented procedures in respect of the retention of records to demonstrate that all certification process requirements have been effectively fulfilled.
The certification related records shall be retained for 5 years. If required by law or any regulation relevant to the product certified, the records shall be retained for longer period in accordance with the relevant regulation.

7.12.2 The BVIPL shall keep records confidential. Records shall be transported, transmitted and transferred in a way that ensures confidentiality is maintained.
The BVIPL shall promptly submit any records sought by BVIPL, Statutory or regulatory body or any government body and facilitate oversight and surveillance as and when required.

The evaluation records shall include records for all product manufacturer, including all applicants evaluated, certified, or certifications suspended or withdrawn. The records of evaluation of manufacturers shall include the following:

i. Application information and results of application review and evaluation man-days estimation.
ii. Evaluation planning and preparation records, evaluation plans and other related records.
iii. justification for evaluation time determination
iv. Records of evaluation reports and related records.
v. Initial and final evaluation records, records of verification.

vi. Records of review and certification decisions; committee deliberations and decisions, if applicable.
vii. Certification agreement.
viii. Certification Documentation (statement of conformity, certificate, etc.), including scope of certification.
ix. Records of complaints and appeals, and any subsequent correction or corrective actions.
x. Related records necessary to establish the credibility of the certification, such as evidence of the competence of evaluators, technical experts, review personnel, and decision makers, etc. as relevant.
xi. Any other records as relevant to the certification process, in order to provide confidence that the certification scheme requirements were complied with.

7.12.3 If the certification scheme involves complete re-evaluation of the product(s) within a determined cycle, records shall be retained at least for the current and the previous cycle. Otherwise, records shall be retained for a period of 5 years or if any specific period mentioned in the contract.

Renewal of Certificate (not applicable)

The statement of conformity shall be renewed at the expiry of 5 years validity period. However, the renewal process and the renewal of certification decision shall be taken on or before the certificate expiration date. In order to achieve the same, the BVIPL shall send the Renewal notice to the certified units at least four months prior to expiry of certificate validity period.

The product manufacturer shall apply for renewal in the prescribed format along with fee, at least 3 months before expiry of the certification. The BVIPLs may process the application and issue the renewal prior to expiry of the certificate.

In case, the applicant doesn't follow the defined timelines, as a result of which the certificate expires, the same may be considered as suspension of the certificate.

The BVIPL shall conduct an onsite evaluation for renewal like that for an initial certification conducted to evaluate the continued fulfilment of all of the requirements of the Certification scheme. All process steps from application to certification decision and issuance of certification documentation. The renewal shall be conducted under the same certificate number such that it is traceable to the previous certification cycle.

The BVIPL shall review the performance of the manufacturer that has sought renewal of the Certificate, with respect to compliance to certification criteria during the entire certification cycle, prior to a decision on the renewal of the certificate. The review shall essentially be based on the following:

i. Renewal evaluation reports for the evaluations carried out during the certification cycle.
ii. Any suspension of certificate (partial and full) during the previous validity period.
iii. corrective actions for suspension on account of administrative reasons taken.
iv. complaints and adverse incident reporting, if any received,
v. Adverse information from stakeholders and regulators, if any.

The review shall be conducted by competent person (s) designated for the job.

The decision for renewal of certificate shall be taken by the competent personnel authorised for the same, based on the satisfactory performance of the product manufacturer as revealed through the review process.

The BVIPL shall not renew certification with conditions for compliance to be verified subsequently. There shall be no conditional renewal of certification.

When performance of the certified unit is not satisfactory, the BVIPL shall withhold the renewal of the certificate and proceed for cancellation.

The renewal shall be affected from the date of the expiry of the previous certificate and the intervening period shall be treated as period of suspension and clearly stated on the Certificate. The manufacturer shall not claim certification or use the Certification Mark during this period.

In case the manufacturer does not complete the administrative requirements satisfactorily actions within three months, the certificate shall stand expired from the date of expiry of previous validity.

Cancellation

BVIPL shall recommend for the cancellation of the certificate to BVIPL when.

i. Certified unit contravenes the terms and conditions of certification and provisions of Certification Scheme.
ii. Product /components failed to comply to the certification criteria.

BVIPL shall recommend of cancelling the certificate at the request of the manufacturer/applicant, if the product manufacturing by manufacturer's premises can no longer be carried due to reasons of natural calamities such as flood, fire, earthquake etc., lock out declared by the management, or closure of business operations etc.

Change of Ownership/Name and change of location.

In case of change of ownership, name and on change of location Bureau Veritas shall advise the certified manufacturer (product / component) to submit a review application to Bureau Veritas for review of the certification criteria.

Extension of scope

When the product manufacturer request for extension of scope of certification already granted, Bureau Veritas shall, obtain this request on a prescribed application form for the purpose for obtaining information on the additional scope of certification along with the necessary documentation and records as are being sought for initial application.

The process of extension of scope shall undergo the same steps from receiving of an application to the decision making as in the case of initial certification as detailed in paragraph 4 onwards.

The extension of scope shall be clearly mentioned in the certificate document/conformity assessment along with its date of inclusion of the Product/component for avoiding any misrepresentation or misinterpretation. Irrespective of the date of inclusion, the validity of the Certificate shall remain unchanged.

Evaluation Fees

Bureau Veritas shall charge a fee to the applicant / certified manufacturer in a non-discriminatory manner.

Bureau Veritas fee structure shall be publicly available & provided on request and also will be part of proposal.

Bureau Veritas shall notify and obtain consent to its fee structure from the product manufacturer prior to grant of certification. As and when the fee undergoes a change, the same shall be communicated to all including applicants and the product manufacturer operating under this scheme of certification for their acceptance.